STIC-Biotech/ChemLib 102491

From: Chan, Christina
Sent: Wednesday, August 27, 2003 12:10 PM
To: Cook, Lisa; STIC-Biotech/ChemLib
Subject: RE: RUSH SEQUENCE SEARCH

Please rush. Thanks Chris

Chris Chan
TC 1600 New Hire Training Coordinator and SPE 1644
308-3973
CM-1, 9B19

-----Original Message-----
From: Cook, Lisa
Sent: Wednesday, August 27, 2003 11:34 AM
To: Chan, Christina
Subject: RUSH SEQUENCE SEARCH

Good morning Christina,

Would you please approve the following rush sequence search for an amendment application.

Thanks,
Lisa

Application Number: 09/845,738

Title: Biopolymer marker indicative of disease state having a molecular weight of 1562 Daltons.

Inventions: George Jackowski
Brad Thatcher
Tammy Vrees
John Marshall

Earliest priority filing date: 4/30/01

Search Request: Sequence search including interference search for SEQ ID NO:1.

Searcher:_____
Phone:_____
Location:_____
Date Picked Up:_____
Date Completed:_____
Searcher Prep/Review:_____
Clerical:_____
Online time:_____

TYPE OF SEARCH:
NA Sequences:_____
AA Sequences:_____
Structures:_____
Bibliographic:_____
Litigation:_____
Full text:_____
Patent Family:_____
Other:_____

VENDOR/COST (where applic.)
STN:_____
DIALOG:_____
Questel/Orbit:_____
DRLink:_____
Lexis/Nexis:_____
Sequence Sys.:_____
WWW/Internet:_____
Other (specify):_____

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BIBDATASHEET

Bib Data Sheet

CONFIRMATION NO. 3448

SERIAL NUMBER	FILING DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
09/845,738	04/30/2001 RULE	436	1641	2132.040

APPLICANTS

George Jackowski, Kettleby, CANADA;

Brad Thatcher, Toronto, CANADA;
Tammy Vrees, Oakville, CANADA;Jason Yantha, Toronto, CANADA;
John Marshall, Toronto, CANADA;

STIC search submitted LYCook 8/26/03 ☺

** CONTINUING DATA **********

** FOREIGN APPLICATIONS **********

IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** SMALL ENTITY **
** 06/26/2001

Foreign Priority claimed 35 USC 119 (a-d) conditions met Verified and Acknowledged	☐ yes ☐ no ☐ yes ☐ no ☐ Met after Allowance Examiner's Signature Initials	STATE OR COUNTRY CANADA	SHEETS DRAWING 2	TOTAL CLAIMS 35	INDEPENDENT CLAIMS 6

ADDRESS
21917
MCHALE & SLAVIN, P.A.
2855 PGA BLVD
PALM BEACH GARDENS , FL
33410

TITLE
Biopolymer marker indicative of disease state having a molecular weight of 1562 daltons

FILING FEE RECEIVED 675	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

8/A
9-9-02

IN RE APPLICANT	: Jackowski et al
INVENTION	: **Biopolymer Marker Indicative of Disease State Having a Molecular Weight of 1562 Daltons**
SERIAL NUMBER	: 09/845,738
FILING DATE	: April 30, 2001
EXAMINER	: N/A
GROUP ART UNIT	: 1743
OUR FILE NO.	: 2132.040

To: The Commissioner of Patents and Trademarks
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir or Madam:

Please enter the following amendment preliminary to examination on the merits, no new matter is added:

IN THE CLAIMS:

3. (New) A method for evidencing and categorizing at least one disease state comprising:

obtaining a sample from a patient;

conducting mass spectrophotometric analysis on said sample;

evidencing and categorizing at least one biopolymer marker sequence or analyte thereof isolated from said sample; and,

comparing said at least one isolated biopolymer marker sequence or analyte thereof to the biopolymer marker sequence as set forth in claim **1**;

wherein correlation of said isolated biopolymer marker and said biopolymer marker sequence as set forth in claim **1** evidences and categorizes said at least one disease state.

4. (New) The method of claim **3**, wherein said step of evidencing and categorizing is particularly directed to biopolymer markers or analytes thereof linked to at least one risk of disease development of said patient.

5. (New) The method of claim **3**, wherein said step of evidencing and categorizing is particularly directed to biopolymer markers or analytes thereof related to the existence of a particular disease state.

6. (New) The method of claim **3**, wherein the sample is an unfractionated body fluid or a tissue sample.

7. (New) The method of claim 3, wherein said sample is at least one of the group consisting of blood, blood products, urine, saliva, cerebrospinal fluid, and lymph.

8. (New) The method of claim 3, wherein said mass spectrophotometric analysis is Surface Enhanced Laser Desorption Ionization (SELDI) mass spectrometry (MS).

9. (New) The method of claim 3, wherein said patient is a human.

10. (New) A diagnostic assay kit for determining the presence of the biopolymer marker or analyte thereof of claim 1 comprising:

at least one biochemical material which is capable of specifically binding with a biomolecule which includes at least said biopolymer marker or analyte thereof, and

means for determining binding between said biochemical material and said biomolecule.

11. (New) The diagnostic assay kit of claim 10, wherein said biochemical material or biomolecule is immobilized on a solid support.

12. (New) The diagnostic assay kit of claim 10 including:

at least one labeled biochemical material.

13. (New) The diagnostic assay kit of claim **10**, wherein said biochemical material is an antibody.

14. (New) The diagnostic assay kit of claim **12**, wherein said labeled biochemical material is an antibody.

15. (New) The diagnostic assay kit of claim **10**, wherein the sample is an unfractionated body fluid or a tissue sample.

16. (New) The diagnostic assay kit of claim **10**, wherein said sample is at least one of the group consisting of blood, blood products, urine, saliva, cerebrospinal fluid, and lymph.

17. (New) The diagnostic assay kit of claim **10**, wherein said marker includes the sequence ID ITHRIHWESASLL and said biochemical material is at least one monoclonal antibody specific therefore.

18. (New) A kit for diagnosing, determining risk-assessment, and identifying therapeutic avenues related to a disease state comprising:

at least one biochemical material which is capable of specifically binding with a biomolecule which includes at least one biopolymer marker including the sequence ID ITHRIHWESASLL or an analyte thereof related to said disease state; and

means for determining binding between said biochemical material and said biomolecule;

whereby at least one analysis to determine a presence of a marker, analyte thereof, or a biochemical material specific thereto, is carried out on a sample.

19. (New) The kit of claim **18**, wherein said biochemical material or biomolecule is immobilized on a solid support.

20. (New) The kit of claim **18** including:

at least one labeled biochemical material.

21. (New) The kit of claim **18**, wherein said biochemical material is an antibody.

22. (New) The kit of claim **20**, wherein said labeled biochemical material is an antibody.

23. (New) The kit of claim **18**, wherein the sample is an unfractionated body fluid or a tissue sample.

24. (New) The kit of claim **18**, wherein said sample is at least one of the group consisting of blood, blood products, urine, saliva, cerebrospinal fluid, and lymph.

25. (New) The kit of claim **18**, wherein said marker includes the sequence ID ITHRIHWESASLL or at least one analyte thereof and said biochemical material is at least one monoclonal antibody specific therefore.

26. (New) The kit of claim **18**, wherein said diagnosing, determining risk assessment, and identifying therapeutic avenues is carried out on a single sample.

27. (New) The kit of claim **18**, wherein said diagnosing, determining risk assessment, and identifying therapeutic avenues is carried out on multiple samples such that at least one analysis is carried out on a first sample and at least another analysis is carried out on a second sample.

28. (New) The kit of claim **27**, wherein said first and second samples are obtained at different time periods.

29. (New) Polyclonal antibodies produced against the marker sequence ID ITHRIHWESASLL in at least one animal host.

30. (New) An antibody that specifically binds a biopolymer including the marker sequence ID ITHRIHWESASLL or at least one analyte thereof.

31. (New) The antibody of claim **30** that is a monoclonal antibody.

32. (New) The antibody of claim **30** that is a polyclonal antibody.

33. (New) A process for identifying therapeutic avenues related to a disease state comprising:

conducting an analysis as provided by the kit of claim 18; and

interacting with a biopolymer including the sequence ID ITHRIHWESASLL or at least one analyte thereof;

whereby therapeutic avenues are developed.

34. (New) The process for identifying therapeutic avenues related to a disease state in accordance with claim **33**, wherein said therapeutic avenues regulate the presence or absence of the biopolymer including the sequence ID ITHRIHWESASLL or at least one analyte thereof.

35. (New) A process for regulating a disease state by controlling the presence or absence of a biopolymer including the sequence ID ITHRIHWESASLL or at least one analyte thereof.

REMARKS

The above additions to the claims find basis in the original disclosure generally at page 12, lines 2 - 12, and at page 16, line 2 to page 18, line 10. Page 6, lines 5 - 20 refer to the use of the specific terms "analyte", "molecular fragmentation" and "fragment ions". By its definition within the specification, immunologic complexes and fragments thereof are therefore included. Page 28, lines 3 - 23 refer to the use of samples which are a variety of blood and blood products and their measurement. Page 29, line 4 refers to known immunoassay techniques and provides an article by Takahashi which is incorporated by reference (page 33, line 3). This article describes the standard use of obtaining more than one sample and at different time periods. Page 31, lines 6 - 8 refer to the use of polyclonal antibodies produced in an animal host. Page 14, lines 18 - 22 refer to the therapeutic avenues to be developed based on interactions observed such as within the complement system in order to regulate the progression of disease involving a form of a biopolymer. It is clear from these specific recitations and from the description of methods utilized to develop therapies based on the specific biopolymer disclosed that the

methods, types of kits and antibodies were fully contemplated by the inventor at the time of filing and were enabled by virtue of the disclosure as originally filed.

Respectfully submitted,

Ferris H. Lander

Ferris H. Lander
Registration # 43,377

Date: August 10, 2001

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Foreign Priority claimed 35 USC 119 (a-d) conditions met Verified and Acknowledged	☐ yes ☐ no ☐ yes ☐ no ☐ Met after Allowance Examiner's Signature Initials	STATE OR COUNTRY CANADA	SHEETS DRAWING 2	TOTAL CLAIMS 35	INDEPENDENT CLAIMS 6

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conducting mass spectrophotometric analysis on said sample;

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comparing said at least one isolated biopolymer marker sequence or analyte thereof to the biopolymer marker sequence as set forth in claim **1**;

wherein correlation of said isolated biopolymer marker and said biopolymer marker sequence as set forth in claim **1** evidences and categorizes said at least one disease state.

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6. (New) The method of claim **3**, wherein the sample is an unfractionated body fluid or a tissue sample.

7. (New) The method of claim **3**, wherein said sample is at least one of the group consisting of blood, blood products, urine, saliva, cerebrospinal fluid, and lymph.

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11. (New) The diagnostic assay kit of claim **10**, wherein said biochemical material or biomolecule is immobilized on a solid support.

12. (New) The diagnostic assay kit of claim **10** including:

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13. (New) The diagnostic assay kit of claim **10**, wherein said biochemical material is an antibody.

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